

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

REGENTS OF THE UNIVERSITY OF
MINNESOTA,

Case No. 07-CV-4732 (PJS/LIB)

Plaintiff,

v.

ORDER ON MOTION FOR SUMMARY
JUDGMENT OF NONINFRINGEMENT

AGA MEDICAL CORPORATION,

Defendant.

Kevin D. Conneely, David D. Axtell, Ruth Rivard, and Erik M. Drange, LEONARD,
STREET AND DEINARD, PA, for plaintiff.

J. Derek Vandenburg, Alan G. Carlson, R.J. Zayed, Tara C. Norgard, and Andrew M.
Mason, CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A., for defendant.

Defendant AGA Medical Corporation (“AGA”) moves for summary judgment that it does not infringe two patents owned by plaintiff Regents of the University of Minnesota (“the University”). For the reasons that follow, the Court agrees with AGA that a reasonable jury could not find that AGA infringes U.S. Patent No. 6,077,291 (the ‘291 patent). But with respect to U.S. Patent No. 6,077,281 (the ‘281 patent), the Court holds that whether AGA infringes the asserted claims is a jury question.

I. BACKGROUND

The University sued AGA for allegedly infringing the ‘281 and ‘291 patents. Both patents cover medical devices for repairing heart defects. The University owns the patents, which are part of a family of four patents covering inventions made by Gladwin S. Das. The University prosecuted all four patents as Das’s assignee.

The Das patents descend from an application filed in 1992. The University abandoned the original application, but subsequent divisional applications resulted in four patents: U.S. Patent No. 5,334,217, issued in April 1994; U.S. Patent No. 5,578,045, issued in November 1996; and the ‘281 and ‘291 patents, both of which were issued on June 20, 2000. These four patents include different claims but generally share the same specification.¹

Roughly speaking, all of the Das patents cover a closure device, commonly called an “occluder,” for repairing a hole between two chambers of a human heart. The occluder is delivered through a catheter that is threaded through a vein or artery until the catheter’s far end reaches the hole to be closed.

The occluder features two disks that are joined at the center. The disks, which are springy, are folded up and pushed through a catheter. The far end of the catheter is placed through the hole in the heart. The occluder is then pushed forward through the catheter until the first of the two disks comes out of the catheter on the far side of the hole and springs back into its disk-like shape. The catheter is then pulled back to the near side of the hole with the second half of the occluder (i.e., the second disk) still inside the catheter. The occluder is pushed forward again until the second disk springs out, this time on the near side of the hole. The area where the two disks are joined blocks the hole, and the disks stay in position for two reasons: (1) they are bigger than the hole, and (2) they are springy. The central portion of the disk eventually becomes solid in one of a number of ways, and at that point, the hole is closed.

¹The abstract of one patent, U.S. Patent No. 5,578,045, differs from the abstract of the other patents. The claims of patent 5,578,045 cover a delivery system for implanting a device for repairing heart defects, not the device itself.

II. CLAIM CONSTRUCTION

In its *Markman* order issued in September 2009 [Docket No. 142], the Court construed various disputed terms found in the claims of the ‘281 and ‘291 patents in accordance with *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996). That order did not put to rest the parties’ disagreements about claim construction, however, as the parties’ summary-judgment briefs demonstrate. The Court therefore addresses below the claim-construction issues that have arisen on summary judgment. In doing so, the Court follows the general principles of claim construction set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

A. “affixed,” “joined,” and “connected”

The Court construes the claims of the ‘291 patent as follows:

The word “disks” in the phrases “first and second occluding disks” and “first and second disks” means “disks that, before being affixed, joined, or connected, exist separately as individual, physically distinct disks.”

This construction is substantively identical to the construction set out in the Court’s earlier *Markman* order. In that order, the Court held:

The phrase “first and second occluding disks” means “physically distinct and separate first and second occluding disks.” The phrase “first and second disks” means “physically distinct and separate first and second disks.”

Markman Order at 5. The Court sees no substantive reason for modifying this construction, the meaning of which was clear from the Court’s earlier *Markman* order. But because the University’s arguments in opposition to summary judgment show that the University either does not understand, or refuses to accept, the clear import of the Court’s earlier construction of the

term “disks” in the phrases “first and second occluding disks” and “first and second disks,” the Court now further clarifies its claim construction.

Perhaps the central infringement question in this case is whether the patents-in-suit cover only devices made from two separate, independently existing disks that are attached to each other, or whether they also cover devices, such as AGA’s, in which two occluding disks are part of a single, integrally formed structure. In their claim-construction briefs, the parties staked out their positions. AGA argued for a claim construction of the terms “affixed,” “joined,” and “connected” that would “require two separate elements that are attached to one another, and [would] exclude a unitary structure.”² AGA Opening *Markman* Br. at 21 [Docket No. 65]. The University opposed construing these terms at all and strenuously objected to AGA’s “attempt[] to limit the [claimed] invention to a device that begins as physically discrete and separate parts — that is, two discrete occluding disks and a separate and physically discrete joining segment.” Univ. Opening *Markman* Br. at 17 [Docket No. 68].

In its *Markman* order, although the Court did not adopt the precise construction of “affixed,” “joined,” and “connected” advocated by AGA, the Court plainly sided with AGA over the University. As the Court said: “AGA’s central point — that the ‘291 patent covers a device with physically separate disks, and that this property of physical separateness is entailed by the patent’s use of the words ‘affix,’ ‘join,’ and ‘connect’ — is well taken.” *Markman* Order at 8. Elsewhere in the order, the Court said that the patentee’s use of the terms “‘bonded,’ ‘sewn,’ and ‘fixed’ by adhesive . . . support[s] the Court’s claim construction because they all suggest that the

²AGA also argued that “in communication with” should be construed together with, and identically to, “affixed,” “joined,” and “connected.” AGA Opening *Markman* Br. at 18-19. The Court discusses “in communication with” separately below.

two disks are physically distinct things that must somehow be joined to one another.” *Id.* at 6 n.4. And if these two statements were not sufficiently clear, the Court also said that “things that are ‘affixed’ are, by that word’s necessary implications, *originally separate*.” *Id.* at 9 (emphasis added).

The University now argues that the phrase “physically distinct and separate disks” in the Court’s original claim construction could cover AGA’s integrally formed occluders because someone looking at an AGA occluder could say that it has two disks. Univ. Mem. Opp. S.J. Regarding Infringement (“Univ. SJ Opp.”) at 17-21 [Docket No. 204]. This argument is based on an unreasonable reading of the Court’s claim-construction order. The Court explained at length in that order why the terms “affixed,” “joined,” and “connected” must be construed to cover a device in which the disks are “originally separate” — in other words, “a device *made by bringing together* two similar, separate, physically distinct disks.” *Markman* Order at 11. The Court continues to believe that its earlier claim construction was correct in substance, and revises its claim construction only to eliminate the (nonexistent) ambiguity that the University attempted to manufacture in opposing AGA’s summary-judgment motion.

B. “in communication with”

The Court construes the term “in communication with” in claims 1 and 2 of the ‘281 patent as follows:

A portion of a first member is “in communication with” a portion of a second member if those two portions are arranged in such a way that movement of one portion is transmitted to the other portion.

This construction supersedes the narrower construction set out in the Court’s earlier *Markman* order. In that order, the Court held:

A portion of a first member is “in communication with” a portion of a second member if those two portions are cavities or tubes whose interior spaces are connected to each other by means of an opening or passageway.

Markman Order at 12.

On further reflection, and after reviewing the parties’ summary-judgment briefs, the Court determined that its earlier construction of “in communication with” was erroneous. Accordingly, after discussing the term with the parties at the summary-judgment hearing, the Court asked for additional briefing on how to construe it.

The ordinary meaning of the phrase “in communication with” seems, at first glance, to be an awkward fit for the device described in the ‘281 patent.³ At its broadest level, “communication” is the transmission of something — e.g., sound, information, electrical signals,

³The Court relies on general-purpose dictionaries and its own knowledge of the English language for the ordinary meaning of the phrase “in communication with.” AGA objects to the Court’s consideration of dictionary definitions as a starting point for construing this term, arguing that the Court’s approach is contrary to *Phillips*. AGA Opening Suppl. *Markman* Br. at 3-5 [Docket No. 215]. In fact, the Court’s approach is entirely consistent with *Phillips*, which said:

[T]here is no magic formula or catechism for conducting claim construction. Nor is the court barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence. For example, a judge who encounters a claim term while reading a patent might consult a general purpose or specialized dictionary to begin to understand the meaning of the term, before reviewing the remainder of the patent to determine how the patentee has used the term. The sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law.

415 F.3d at 1324 (citations omitted).

radio waves, disease, air, fluid, or movement — from one thing, person, or location to another.⁴

At a more-specific level, the physical relationship of “communication” typically describes a relationship among items, such as rooms or tubes, that have interior spaces that are connected to one another.⁵

Despite the apparent oddness of the word “communication” in claim 1 of the ‘281 patent, the patent’s drafter was plainly familiar with the ordinary meaning of “communication” with respect to physical objects. On two occasions, the written-description section of the ‘281 patent uses a form of the word “communication” in something close to its ordinary meaning.

First, in describing a delivery system for the claimed occluder, the ‘281 patent says that a “chamber 216 must extend through the distal end 211 of the housing to define a distal port 219

⁴*Webster’s Third New International Dictionary* (“*Webster’s Third*”) defines “communication” in part as:

1: the act or action of imparting or transmitting <the [communication] of the common cold> <the [communication] of power to the machine> . . . 5a: access between persons or places: opportunity of communicating

Webster’s Third New International Dictionary at 460 (1981).

The third edition of the *American Heritage Dictionary* (“*AHD Third*”) defines “communication” in part as:

1. The act of communicating; transmission. 2.a. The exchange of thoughts, messages, or information, as by speech, signals, writing, or behavior. . . . 3. Something communicated; a message.

American Heritage Dictionary of the English Language at 383 (3d ed. 1996).

⁵*Webster’s Third* defines “communicate” in part to mean “be connected: open into each other: afford unbroken passage: *join* <the two rooms [communicate]> <the pantry [communicates] with the hall>.” *Webster’s Third* at 460. *AHD Third* defines “communicate” in part to mean “be connected: *apartments that communicate.*” *AHD Third* at 383.

therein . . . to permit *communication* of the control means 230 with the catheter C.” ‘281 patent col. 13:63-66 (emphasis added). The “control means” referred to in this sentence is connected to a “tubular urging member” that rides within the catheter. ‘281 patent col. 15:16-26. Although the Court said in its earlier *Markman* order that the relationship between the control means and the catheter was only communication “in a loose sense,” *Markman* Order at 15, on further reflection, the Court finds that one could also say that the control means communicates with the *lumen* of the catheter in an *ordinary* sense. Specifically, the control means transmits movement to an urging member, and that member’s movement occurs within the catheter’s lumen. Further, the lumen of a catheter is the type of interior space, such as a room or a tube, that is usually associated with physical communication.

Second, the ‘281 patent says that the claimed invention “can be used to treat ventricular septal defects, patent ductus arteriosus[,] or any other congenital or acquired *orificial or tubular communications* between vascular chambers or vessels.” ‘281 patent col. 18:1-4 (emphasis added). Such “orificial or tubular communications” are holes or tubes that connect items — chambers or vessels — that have interior spaces.

But the preferred embodiments described in the ‘281 patent’s written-description section do not include interior spaces through which substances are transmitted. Indeed, the embodiment depicted in figures 3 through 11 and described at the greatest length consists of two flat disks attached at their centers. This embodiment has no cavity, lumen, or other type of interior space at all.

The embodiment depicted in figure 12, by contrast, is made up of two disks, each of which is a “collapsible balloon-type member which can be inflated to define an internal

cavity” ‘281 patent col. 8:48-49. But the internal cavities of the two members do not open into each other; rather, each cavity is independently inflated by means of its own valve. ‘281 patent col. 8:65-67 to col. 9:1-9. Thus, the cavities of the balloon-type members do not “communicate” in the way that chambers of the heart communicate across a septal defect.

Because the embodiments described in the ‘281 patent do not have disks with interior spaces that communicate substances to each other, AGA argues that the term “in communication with” simply makes no sense and should be replaced with the phrase “attached to.” *See* AGA Opening *Markman* Br. at 20 (“[T]he phrase ‘in communication with’ does not make sense in the way that it is used in claim 1 of the ‘281 patent.”); AGA Opening Suppl. *Markman* Br. at 12 (“‘In communication with’ is a totally inappropriate phrase in the context of the Das patents.”). AGA brushes aside the two instances in the patent’s written description of the word “communication,” arguing that these instances are “not helpful” because “communication” is not used with respect to the claimed invention. AGA Opening Suppl. *Markman* Br. at 6. After declaring irrelevant the patentee’s own use of the word “communication,” AGA argues that because the embodiments described in the patent all feature disks that are attached to each other, the Court should construe “in communication with” to mean “attached to.” *Id.* at 6-10.

The Court rejects AGA’s proposed construction for several reasons. To begin with, AGA is effectively asking the Court to disregard claim language and confine claim 1 of the ‘281 patent to the disclosed embodiments. But the Federal Circuit has long prohibited this very approach to claim construction. *Phillips*, 415 F.3d at 1323 (“[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.”). Moreover, claim 2 of the ‘281 patent covers “[t]he device of

claim 1, wherein the portions of the disks in communication with another are *attached to* one another to define a conjoint disk.” ‘281 patent col. 18:25-27 (emphasis added). This strongly suggests that attachment is a *type* of “communication” envisioned by claim 1, but is not the *only* such type of communication. And, as discussed below, the prosecution history further reinforces the suggestion that “in communication with” encompasses, but is broader than, “attached to.”

The Court also rejects the University’s proposed construction. The University argues that “in communication with” means “connected . . . by means of an opening or passageway, for passage of fluid such as blood.” Univ. Opening Suppl. *Markman* Br. at 2 [Docket No. 212].

This proposed construction has the advantage of being consistent with at least one of the two appearances of the word “communication” in the patent’s specification. But it has the distinct disadvantage of failing to cover the preferred embodiments disclosed in the specification. And “it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in th[e] field would read the specification in such a way.” *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996).

As noted, the embodiment pictured in figures 3 through 11 consists of two flat disks attached at their centers. Although the membrane at the center of the disks is preferably “relatively porous,” ‘281 patent col. 10:5, that membrane — which ceases being porous not long after implantation, *id.* col. 10:8-11 — cannot itself be considered an “opening,” and there is nothing between the two disks that remotely qualifies as a “passageway.” Further, although the balloon-type embodiment depicted in figure 12 includes central tubular segments that could be passageways, those tubular segments are arranged in such a way that fluid is not communicated

between them. Instead, each segment is filled with fluid by means of its own separate valve.
‘281 patent col. 9:2-9.

Although the Court expressed a willingness in its earlier *Markman* order to interpret “in communication with” in such a way that claim 1 of the ‘281 patent would not cover the disclosed embodiments, *see Markman* Order at 16, the Court on further reflection does not believe that such an unlikely result is called for. In particular, the Court finds that both the prosecution history and the written description of the ‘281 patent support construing “in communication with” broadly enough to cover the disclosed embodiments.

As the Court noted in its earlier *Markman* order, the drafter of the ‘281 patent used claim language that was broader than the corresponding language in earlier patents in the same family. *Markman* Order at 13. Those earlier patents generally cover “disks” whose central portions are “affixed” to each other. *See, e.g.*, ‘291 patent claim 1; U.S. Pat. No. 5,334,217 claim 1. But in claim 1 of the ‘281 patent, the drafter substituted the nonspecific term “member” for the more-specific term “disk,” in an obvious attempt to claim the patented invention more broadly than earlier patents did. Similarly, the drafter substituted the broad term “in communication with” for the narrower term “affixed.” A person of ordinary skill in the art would understand, in reading claim 1 of the ‘281 patent and the associated prosecution history, that the drafter was using “in communication with” to include — but also to go beyond — relationships of attachment or affixation.

Further, two items can be “in communication with” each other even if they are not physically attached. In particular, *movement* can be communicated between two objects that merely touch each other — for instance, two palms pressed together, or two books shelved next

to each other — even if those objects are not “attached.” And the ‘281 patent’s description of “communication” between a delivery system’s control means and a catheter relates to the communication of movement — movement of the control means is communicated to a tubular urging member, and the movement of that member takes place within the catheter’s lumen. *See* ‘281 patent col. 13:63-66, col. 15:16.

Movement is likewise transmitted between the disks in each of the two preferred embodiments disclosed in the ‘281 patent. In the flat-disk embodiment depicted in figures 3 through 11, the central portions of the disks are attached to form a conjoint disk, and the central portions therefore move as a unit. Similarly, in the balloon-type embodiment, after the two concentrically arranged central tubular segments are filled with the “preferred” type of fluid, namely some kind of glue or cement, those two segments become united.⁶ The Court’s revised construction of the term “in communication with” therefore covers the disclosed embodiments, is consistent with the patent’s written description and prosecution history, and conforms to one of the ordinary meanings of the word “communication” when that word describes a physical relationship.

C. “tautly holding”

The Court construes the term “tautly holding” in claim 1 of the ‘291 patent and in claim 1 of the ‘281 patent as follows:

⁶‘281 patent col. 9:35-41 (“Although any suitable fluid may be used [to inflate the balloon-type members], it is preferred that a biologically compatible, self-curing cementitious material, such as an epoxy or cyanoacrylate, be used. In this manner, the cavity 121 may be filled with this material and permitted to substantially harden, creating a stable, generally rigid structural member from the membrane 122.”).

The term “tautly holding” derives from the phrase “to hold tautly.” “To hold something tautly against a septum” means both (1) to hold that thing itself taut, like a drum head or the surface of an inflated balloon, and (2) to hold that thing tightly against a septum.

This construction is substantively identical to the construction set out in the Court’s earlier *Markman* order. In that order, the Court held:

The term “tautly holding” derives from the phrase “to hold tautly.” “To hold something tautly against a septum” means both (1) to hold that thing itself taut, like a drum head, and (2) to hold that thing tightly against a septum.

Markman Order at 16. The Court sees no substantive reason for modifying this construction, the meaning of which was clear from the Court’s earlier *Markman* order. But because AGA’s arguments in support of summary judgment show that AGA either does not understand, or refuses to accept, the meaning of the Court’s claim construction with respect to the term “tautly holding,” the Court now further clarifies that claim construction.

AGA has aggressively sought to persuade the Court to construe the patents-in-suit to require a frame around each occluding disk, for the simple reason that AGA’s accused devices do not incorporate a frame. In AGA’s opening claim-construction brief, it sought to insert this frame requirement into the language of claim 1 of the ‘281 patent that calls for “a self-expanding structure exhibiting a spring-like behavioural component.” See AGA Opening *Markman* Br. at 28-37. AGA argued that this was a means-plus-function limitation and that the associated structure was a “frame extending circumferentially around the periphery of a membrane.” *Id.* at 33.

The Court expressly rejected this argument. The Court construed “a self-expanding structure exhibiting a spring-like behavioural component” to be a means-plus-function limitation

with two possible corresponding structures, the first “a flexible, elastically deformable frame carried around the periphery of the member,” and the second “a *frameless* membrane made of a thin piece of a superelastic material.” *Markman* Order at 21 (emphasis added). In explaining this construction, the Court said that the patent “link[ed] a frameless, superelastic membrane to the claimed function” of this means-plus-function limitation. *Id.* at 25.

The Court did not, in its earlier *Markman* order, either endorse or reject the argument that AGA makes now — namely, that the term “tautly holding” calls for a frame that does the holding. The Court did not address the argument for a simple reason: AGA never made it.

AGA’s proposed construction of the term “tautly holding” did not include the word “frame.”⁷ Nor did AGA refer to a frame when it summarized the “primary purpose” of its proposed construction:

The primary purpose of construing [“tautly holding”] is to make clear that there are two separate requirements to the phrase “tautly holding . . . against a septum.” The first requirement is that a specified portion of the device . . . must be held “taut,” i.e., pulled tightly so as to remove slack. The second, separate, requirement is that the specified portion of the membrane/closure device must be held against the septum.

AGA Opening *Markman* Br. at 26.

⁷With respect to claim 1 of the ‘291 patent, AGA asked the Court to hold that “[i]n one position, the membrane must both (i) pull a portion of the membrane tightly so as to remove all slack from that portion of the member and (ii) maintain that portion of the member in intimate contact with the septum.” AGA Opening *Markman* Br. at 25. With respect to claim 1 of the ‘281 patent, AGA asked the Court to hold that “[i]n one position, the member must both (i) pull a portion of the closure device tightly so as to remove all slack from that portion of the closure device and (ii) maintain that portion of the closure device in intimate contact with the septum.” *Id.* at 25-26.

In its *Markman* order, the Court adopted in substance AGA's proposed construction. But the Court reworded AGA's proposed language slightly, to make it more juror-friendly, and added the phrase "like a drumhead" after the word "taut." The Court could have incorporated a dictionary definition of "taut" into its claim construction, but the Court chose instead to use a simile that would bring the word to life in plain, simple terms.

No reasonable reader of the Court's *Markman* order could believe that the Court, by using the words "taut, like a drumhead," intended to construe the patents-in-suit as calling for a frame that pulls the surface of an occluding disk tight. When the Court addressed that argument directly in construing the phrase "a self-expanding structure exhibiting a spring-like behavioural component," the Court rejected it. The Court likewise rejects AGA's attempt to insert a frame limitation into the phrase "tautly holding" because, as explained in the earlier *Markman* order, the patentee unmistakably claimed a frameless embodiment of the invention. *See Markman* Order at 24-25. In changing the phrase "like a drumhead" found in the Court's earlier claim construction to the phrase "like a drum head or the surface of an inflated balloon," the Court both expressly forecloses AGA's argument that only a frame can create tautness, and uses a vivid simile that will help jurors understand and apply the claim language.

D. "members"

Claim 1 of the '281 patent is directed to a device with a "first member" and a "second member." Neither AGA nor the University initially asked the Court to construe the term "member" or identified it as a disputed term in their joint claim-construction statement. The closest the parties came to seeking a construction of the term "member" was the parties' request that the Court construe "in communication with," which is found in claim 1 of the '281 patent

and describes the relationship between “at least a substantial portion of the central portion” of the first and second members. *See* AGA Opening *Markman* Br. at 19; Univ. Opening *Markman* Br. at 22.

AGA now asks the Court to construe “member” so that claim 1 of the ‘281 patent “requires physically distinct and separate members and excludes a unitary structure.” AGA Mem. Supp. Mot. S.J. Noninfringement (“AGA SJ Mem.”) at 13 [Docket No. 197]. The Court declines to do so.

The term “member” is an ordinary term used in its ordinary sense in the ‘281 patent, as shown by the fact that the parties — who have not been reluctant to dispute the meaning of claim terms — did not identify it as a disputed term earlier in this litigation. Further, as discussed above, the prosecution history of the ‘281 patent shows that the patentee chose the terms “member” and “in communication with” to replace the terms “disk” and “affixed,” respectively, in an effort to broaden the claims. Nothing in the prosecution history or the intrinsic evidence supports giving “member” a meaning narrower than its ordinary meaning.

Further, AGA is mistaken in asserting that, for the same reasons that the Court initially construed “disks” in the ‘291 patent as “physically distinct and separate disks,” the term “member” in the ‘281 patent should be interpreted to mean “physically distinct and separate members.” *See* AGA SJ Mem. at 13-14. The Court’s construction of “disks” in the ‘291 patent was driven largely by that patent’s use of the terms “affixed,” “joined,” and “connected” to describe the relationship between the disks. But the ‘281 patent uses the broader term “in communication with,” a term that does not carry the implications of separateness that are carried by “affixed,” “joined,” and “connected.” The Court has now construed “in communication with”

for a second time, and the Court sees no reason to separately construe the ordinary word “member.”

III. SUMMARY JUDGMENT

A. Standard of Review

Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A dispute over a fact is “material” only if its resolution might affect the outcome of the lawsuit under the substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A dispute over a fact is “genuine” only if “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Id.* “The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Id.* at 255.

B. ‘291 Patent — “disks”

AGA argues that its occluders do not infringe the ‘291 patent because they are made from a single, integrally formed tube of nitinol mesh, rather than from two separate disks.⁸ The Court agrees.

For reasons given above and in the Court’s earlier *Markman* order, the Court holds that the “disks” called for in the claims of the ‘291 patent must be “disks that, before being affixed, joined, or connected, exist separately as individual, physically distinct disks.” No reasonable jury could find that the accused occluders have such disks. The fact that AGA’s marketing literature

⁸Certain of AGA’s occluders are accused in connection with an accused *method* rather than, or in addition to, being accused of infringing as standalone devices. For simplicity’s sake, the Court refers to an accused “device” or “occluder,” which means both an occluder accused of infringing a device claim and an occluder that is used in a method accused of infringing a method claim.

describes its occluders as having two disks does not change this conclusion, nor does the fact that medical professionals, including the University's expert, describe AGA's occluders as two-disk devices. *See Univ. SJ Opp.* at 17-21.

The Court agrees that, loosely speaking, AGA's occluders each have two disks. But infringement is not based on the loose meaning of the term "disks"; it must be based on the Court's claim construction. Under that claim construction, AGA's accused occluders do not have "disks" and therefore do not infringe the '291 patent.

C. '281 Patent — "members"

AGA also argues that because its accused occluders are made from a single, integrally formed tube of nitinol mesh, the occluders do not infringe the '281 patent because they lack "members." AGA SJ Mem. at 12-14. The Court disagrees.

As the Court explained above, the term "members" has its ordinary meaning in the '281 patent. A reasonable jury could consider the two disk-like portions of an AGA occluder to be "members," even though they are part of an integrally formed device.

D. '281 Patent — "in communication with"

AGA argued, based on the Court's earlier construction of the term "in communication with," that its accused occluders do not infringe the '281 patent because they lack "at least a substantial portion of the central portion" of first and second members "in communication with" each other. AGA SJ Mem. at 19-25. AGA's argument rested in part on its assertion that "[a] cavity with an interior space" — something called for by the Court's earlier (erroneous) claim construction — "must be bounded by a solid or impermeable surface, which is absent in the

AGA devices.” *Id.* at 21. This assertion about the nature of cavities has no basis in the Court’s *Markman* order, and if it were necessary, the Court would reject AGA’s “porosity” argument.

But the Court has substantially revised its construction of the term “in communication with,” and AGA’s summary-judgment arguments with respect to this term are no longer germane in light of that revised construction. The Court therefore denies without prejudice AGA’s motion for summary judgment that the accused devices do not infringe because they lack central portions “in communication” with one another. The Court notes, however, that based on what the Court knows at this point, a jury will almost surely have to decide whether an accused device meets the “in communication with” limitation.

E. ‘281 and ‘291 patents — “tautly holding”

AGA argues that its occluders do not infringe the patents-in-suit because the occluders lack frames and therefore do not meet the “tautly holding” limitation. AGA SJ Mem. at 14-19. The Court rejects this argument. As the Court’s revised claim construction makes clear, the “tautly holding” limitation requires only that a disk’s surface *be* taut; it does not matter whether the tautness is created by a frame, by the properties of a frameless surface, or by something else.

AGA also argues that the University’s expert is not qualified to opine about whether a surface is taut or not. AGA SJ Mem. at 18-19. The Court disagrees. In this case, a jury will have to decide whether AGA’s devices meet the “tautly holding” limitation of the ‘281 patent. The University’s expert is clearly qualified to testify as to the physical properties of the accused devices after implantation, and thus he is clearly qualified to offer an opinion on whether a portion of an accused device is “taut.”

F. '291 patent — ratio limitations

Three claims in the '291 patent include limitations directed to the ratio between the size of an occluding disk on one side of a defect to be closed and the size of the defect itself (or, what amounts to basically the same thing, of the conjoint disk within that defect).⁹ Specifically, claim 1 of the '291 patent covers a device in which the diameter of an occluding disk is “between about 1.6 and about 2.5 times the diameter of the conjoint disk.” Claims 18 and 23 of the '291 patent are both directed to a method involving a device in which the diameter of an occluding disk is “at least about 1.6 times the diameter of the defect.”

The parties agree that whether an accused device literally meets a ratio limitation is a jury question.¹⁰ But AGA seeks summary judgment that the University should be foreclosed from arguing that an accused device that does not literally meet a ratio limitation nevertheless meets the limitation under the doctrine of equivalents. AGA SJ Mem. at 26-30. Although the Court grants summary judgment of noninfringement with respect to the '291 patent to AGA because AGA's accused occluders do not include “disks,” the Court addresses AGA's argument with respect to the ratio limitations for the sake of completeness.

Under the doctrine of equivalents, an accused product or process that does not literally meet a claim limitation “may nonetheless be found to infringe if there is ‘equivalence’ between

⁹Claim 3 of the '281 patent also includes a ratio limitation: It covers a device in which “a maximum dimension of at least one of the first and second members is between about 1.6 and about 2.5 times a diameter of the conjoint disk.” But the University has not accused AGA of infringing claim 3 of the '281 patent. *See* Docket No. 226, Schedules A-B.

¹⁰*See* SJ Hr'g Tr. at 43:3-5 [Docket No. 211] (“[W]ith respect to the literal infringement question, [AGA is] not disputing that that issue should go to the jury of how much is ‘about.’”); *id.* at 82:7-8 (according to the University's counsel, “[i]t is for the jury to decide” whether, for example, 1.42 is “about” 1.6).

the elements of the accused product or process and the claimed elements of the patented invention.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). The Court agrees with AGA that the doctrine of equivalents is unavailable with respect to the ratio limitations in claims 1, 18, and 23 of the ‘291 patent.

Significantly, the ratio limitations are inherently imprecise. Claim 1 does not require that an occluding disk’s diameter be “between exactly 1.6 and exactly 2.5 times” the size of the conjoint disk’s diameter — nor even that an occluding disk’s diameter be “between 1.6 and 2.5 times” the size of the conjoint disk’s diameter. Rather, Claim 1 requires merely that the occluding disk’s diameter be “between *about* 1.6 and *about* 2.5 times” the conjoint disk’s diameter. Likewise, claims 18 and 23 do not require that an occluding disk’s diameter be “at least exactly 1.6 times” the defect’s diameter or even “at least 1.6 times” the defect’s diameter; rather, they require merely that the occluding disk’s diameter be “at least *about* 1.6 times” the defect’s diameter.

Courts typically decide the meaning of qualifiers such as “about” as a matter of claim construction. For instance, in *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, the Federal Circuit held, based on the patent’s specification and expert testimony, that the term “weight ratio of about 1:5” was properly construed to “encompass[] a range of ratios no greater than 1:3.6 to 1:7.1.” 476 F.3d 1321, 1328 (Fed. Cir. 2007) (quoting, and endorsing, the district court’s claim construction). And in *Cohesive Technologies, Inc. v. Waters Corp.*, the Federal Circuit construed particles of “about 30 μm ” to definitely *include* particles of 25.434 μm or more and to definitely *exclude* particles of 23.044 μm or less. 543 F.3d 1351, 1369-70 (Fed. Cir. 2008). As for particles between these two sizes, the Court found that a

“functional approach” was called for and held that such particles literally meet the “about 30 μm ” limitation if the particles are “of sufficiently large size to assure that a column containing the particles is capable of attaining turbulence.” *Id.* at 1370. More generally, the meaning of the qualifier “about” in a patent claim “depends on the technological facts of the particular case.” *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995).

In this case, however, neither party has asked the Court to construe the term “about” as it appears in the ratio limitations found in claims 1, 18, and 23 of the ‘291 patent. The only question, then, is whether — and if so, how — the doctrine of equivalents applies to these limitations.

Federal Circuit case law is inconsistent with respect to how the doctrine of equivalents interacts with inherently fuzzy claim limitations, such as limitations that use terms like “about” or “approximately.”¹¹ In *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, the Federal Circuit held that a pH of 5.0 could, under the doctrine of equivalents, meet a limitation calling for

¹¹In arguing that the doctrine of equivalents is available with respect to the challenged ratio limitations, the University relies on cases in which courts have allowed the doctrine of equivalents to be applied with respect to numerical limitations. Univ. SJ Opp. at 45-47. But two of these cases involve numerical limitations that are precise, not fuzzy. See *U.S. Philips Corp. v. Iwasaki Elec. Co.*, 505 F.3d 1371, 1373 (Fed. Cir. 2007) (limitation at issue calls for halogen “in a quantity between 10^{-6} and 10^{-4} $\mu\text{mol}/\text{mm}^3$ ”); *Synergetics, Inc. v. Peregrine Surgical, Ltd.*, 427 F. Supp. 2d 537, 550 (E.D. Pa. 2006) (limitation at issue was construed to require slots that “fall within minimum and maximum diameters of .091 and .097 inches”); see also *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1100, 1107-08 (Fed. Cir. 2002) (where limitation at issue specifies that “overall phospholipid content is 68.6–90.7%,” court holds that “[t]he fact that a claim recites numeric ranges does not, by itself, preclude [the patentee] from relying on the doctrine of equivalents”).

Cases involving precise numerical limitations are beside the point. The issue in this case is not whether the doctrine of equivalents applies to *precise* numerical limitations; it is whether the doctrine of equivalents applies to *fuzzy* numerical limitations.

a pH of “approximately 6.0.” 114 F.3d 1161, 1164 (Fed. Cir. 1997). This implies that the doctrine of equivalents is available with respect to fuzzy claim limitations. But the patentee in *Warner-Jenkinson* brought claims only for infringement under the doctrine of equivalents, not for literal infringement. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 23 (1997) (“Hilton Davis conceded that there was no literal infringement, and relied solely on the doctrine of equivalents.”). And there is no indication in the Federal Circuit’s or the Supreme Court’s *Warner-Jenkinson* opinions that the accused infringer ever argued — as does AGA — that the doctrine of equivalents should be unavailable for expressly fuzzy limitations.

The Federal Circuit, however, held in *Cohesive Technologies* that the doctrine of equivalents could not be applied with respect to a limitation calling for particles of “about 30 μm ” in diameter. 543 F.3d at 1372. After construing “about 30 μm ” to include particles between 23.044 μm and 25.434 μm only if the particles were large enough “to assure that a column containing the particles is capable of attaining turbulence,” *id.* at 1370, the court said that “by electing to include the broadening word ‘about’ in the claim, the patentee has . . . already captured what would otherwise be equivalents within the literal scope of the claim,” *id.* at 1372. Accordingly, the court held that “[w]here, as here, a patentee has brought what would otherwise be equivalents of a limitation into the literal scope of the claim, the doctrine of equivalents is unavailable to further broaden the scope of the claim.” *Id.*

Further, in *Ortho-McNeil*, the Federal Circuit reached an outcome similar to that in *Cohesive Technologies*, though it apparently arrived at the outcome by a different route. At issue in *Ortho-McNeil* was a ratio limitation of “about 1:5,” which was construed to “‘encompass[] a range of ratios no greater than 1:3.6 to 1:7.1.’” 476 F.3d at 1328. In upholding a finding that a

formula with a ratio of “no less than 1:7.5” did not meet this limitation under the doctrine of equivalents, the Federal Circuit said that the patentee could not argue that the “about 1:5” ratio limitation “is broad enough to encompass, through the doctrine of equivalents, ratios outside of the confidence intervals expressly identified in the patent.” *Id.* Because the confidence intervals identified in the patent were a key consideration in construing the literal scope of “about 1:5,” *see id.*, this statement appears to be equivalent to the statement in *Cohesive Technologies* that the doctrine of equivalents is unavailable to broaden a fuzzy claim limitation beyond its literal scope.

But *Ortho-McNeil* also said that the intrinsic evidence “necessitates a . . . range of equivalents that does not encompass” a formula with the ratio of no less than 1:7.5, *id.* at 1329 (emphasis added) — which suggests that the patentee could rely on some *narrower* range of equivalents (rather than *no* range of equivalents) to establish that the limitation was met. Further, *Ortho-McNeil* based its holding in the doctrine of “claim vitiation,” saying that to find that “no less than 1:7.5” was equivalent to “about 1:5” would “eviscerate the limitation.” *Id.* Yet *Cohesive Technologies* made no mention of the claim-vitiation doctrine, even though both *Cohesive Technologies* and *Ortho-McNeil* reached a similar holding — namely, that the doctrine of equivalents did not cover a value outside of a fuzzily claimed numerical range once the boundaries of that range had been determined by means of claim construction.

Under the claim-vitiation doctrine (which follows from the principle that a claim is infringed only if all claim limitations are met), a party may not rely on the doctrine of equivalents with respect to a particular limitation if a finding of equivalence would “read[] [that limitation] completely out of the claims.” *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1362 (Fed. Cir. 2005). According to AGA, the claim-vitiation doctrine (among other things) prevents

the University from relying on the doctrine of equivalents to show that a ratio limitation is met by a device that does not literally meet the limitation. AGA SJ Mem. at 29-30. AGA treats the claim-vitiation argument as separate from the argument that, under *Cohesive Technologies*, the doctrine of equivalents cannot be used with respect to fuzzy claim limitations.

As the Court reads *Cohesive Technologies* and *Ortho-McNeil*, however, the rule articulated in *Cohesive Technologies* against applying the doctrine of equivalents to fuzzy claim limitations is really just an instance of the application of the claim-vitiation doctrine. When a patentee uses an exact number in a claim, the patentee can use the doctrine of equivalents to reach above or below that exact number by some amount. *See, e.g., Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097, 1107-08 (Fed. Cir. 2002) (“The fact that a claim recites numeric ranges does not, by itself, preclude [the patentee] from relying on the doctrine of equivalents.”). Expanding an exact number through the doctrine of equivalents does not vitiate a precise numerical limitation; it simply gives to a precise numerical limitation the flexibility that is given to every other type of limitation.

But when a numerical limitation is fuzzy to begin with, to allow the patentee to reach numbers outside the already-expanded range captured by the literal claim language is to say, in effect, that the fuzzy limitation is irrelevant. Indeed, in this very case, the University’s theory of equivalence for the ratio limitations renders them irrelevant. As the University would have it, a device can meet the “about 1.6” ratio limitation under the doctrine of equivalents regardless of the numerical ratio of the diameters of a disk and a defect, as long as the disk “anchor[s] the device (so that no deployed occluding disc portions will be readily drawn through the defect) without negatively interfering with the structure or function of the heart.” Univ. SJ Opp. at 46.

In other words, as the University would have it, as long as an occluding device *works*, the ratio between the disks and the defect could be *anything*. The Court agrees with AGA that the University's theory of equivalence vitiates the ratio limitations, just as the Court agrees with AGA that under *Cohesive Technologies*, the doctrine of equivalents is not available to expand the scope of the already-fuzzy ratio limitations beyond their literal reach.

Further, the Court agrees with AGA's alternative argument that prosecution-history estoppel bars the University from applying the doctrine of equivalents to the ratio limitations at issue. *See* AGA SJ Mem. at 26-29. The doctrine of prosecution-history estoppel prevents a patentee from reclaiming, through the doctrine of equivalents, that portion of a claim's scope that was surrendered in the course of prosecution to gain allowance of a patent. *See Hughes Aircraft Co. v. United States*, 140 F.3d 1470, 1476 (Fed. Cir. 1998) (“[T]he key to prosecution history estoppel is the surrender or disclaimer of subject matter by the patentee, which the patentee is then unable to reclaim through the doctrine of equivalents.”).

Thus, prosecution-history estoppel applies only when a patentee makes a narrowing amendment — i.e., an amendment that surrenders a portion of a claim's scope. *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) (“To determine whether a claim gives rise to prosecution history estoppel, we first must determine whether the amendment narrowed the literal scope of the claim.”). When a patentee does make a narrowing amendment, the patentee bears the burden of rebutting the presumption that the amendment was made for purposes of patentability — a presumption that, if left un rebutted, leads to prosecution-history estoppel. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002) (“A patentee's decision to narrow his claims through amendment may be presumed to be

a general disclaimer of the territory between the original claim and the amended claim.”); *Warner-Jenkinson*, 520 U.S. at 33.

In the application that led up to the ‘291 patent, the ratio limitations were added in a supplemental amendment that was not made in response to an action by the PTO. *See* JA 361-67¹² (April 25, 1997 amendment effectively adding initial version of claims after correcting PTO’s misunderstanding about earlier submissions); JA 371-85 (May 14, 1997 supplemental amendment amending claims submitted in the April 25, 1997 amendment). The Court is uncertain whether the University contends that the ratio limitations, when they were added by supplemental amendment, did not narrow the claims and therefore cannot give rise to prosecution-history estoppel. If the University is making this argument, the Court rejects it. The claims *without* the ratio limitations (found in the April 25, 1997 amendment) are plainly broader than the claims *with* the ratio limitations (found in the May 14, 1997 amendment).

The University therefore bears the burden of establishing that the ratio limitations were not added for purposes of patentability. *Pioneer Magnetics, Inc.*, 330 F.3d at 1356. The University has not borne this burden.

The University appears to argue that because the ratio limitations were not added in response to an office action, they must not have been added for purposes of patentability. Univ. SJ Opp. at 40-41. But in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, the Federal Circuit held that prosecution-history estoppel applied with respect to a limitation that was added in a

¹²The parties filed a joint appendix containing materials relevant to claim construction [Docket No. 70]. Each page in the joint appendix has a page number beginning with the prefix “APP-.” The Court cites these materials as “JA [page number]”; thus, for instance, “JA 204” corresponds to the page numbered “APP-00204.”

preliminary amendment “to preempt a double-patenting rejection” 457 F.3d 1293, 1310, 1316 (Fed. Cir. 2006). Under *Amgen*, then, prosecution-history can apply not only to amendments made in *response* to rejections, but also to amendments made to *preempt* rejections.

AGA contends that the ratio limitations were added to preempt a rejection over U.S. Pat. No. 3,874,388 to King — a patent that the PTO had relied on to reject claims in an earlier, related application. AGA SJ Mem. at 27-28; JA 940 (PTO office action rejecting claims in application 07/822,951 as anticipated by King), 975-78 (applicant’s response challenging rejection and distinguishing King). The University denies that the PTO would have relied on King to reject what became claims 1, 18, and 23 of the ‘291 patent. Univ. SJ Opp. at 42-44. According to the University, the inclusion of the term “conjoint disk” in the claims at issue would have sufficed to distinguish them over King. *Id.*

It is certainly possible that, as the University argues, the disputed claims in the ‘291 patent would have been patentable even without the ratio limitations. But the University must do more than show a possibility that the ratio limitations were not added for purposes of patentability. Instead, the University bears the burden of rebutting the presumption that the ratio limitations were added for purposes of patentability.

Instead of offering argument or evidence to rebut that presumption, the University argues that “the record is devoid of any indication that the ratio elements were added due to patentability, and therefore that language [i.e., the ratio limitations] was, at most, tangential to patentability.” Univ. SJ Opp. at 45. As this quoted language shows, the University has it backwards: It is not AGA’s job to show an “indication” in the record that the ratio limitations

“were added due to patentability”; it is the University’s job to establish that they were *not* added for purposes of patentability. The University has not done so.

Finally, a word about literal infringement: The University decided, without the benefit of a construction of the term “about,” to accuse certain occluders of meeting the ratio limitation literally and other occluders of doing so under the doctrine of equivalents. *See* Docket No. 226. In singling out certain occluders that it does not accuse of meeting the ratio limitation literally, the University effectively conceded that those occluders do not have disk-to-defect ratios of “between about 1.6 and about 2.5” or “about 1.6.” If a trial were necessary with respect to infringement of the ‘291 patent, the University would be foreclosed from accusing of literal infringement those occluders that it accused, in its claim chart, only of infringement under the doctrine of equivalents.

ORDER

Based on the foregoing and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT:

1. Defendant AGA Medical Corporation’s motion for summary judgment of noninfringement [Docket No. 195] is GRANTED IN PART as follows:
 - a. Count 1 of plaintiff Regents of the University of Minnesota’s first amended complaint [Docket No. 79] for infringement U.S. Patent No. 6,077,291 is DISMISSED WITH PREJUDICE AND ON THE MERITS.
 - b. The Court DECLARES, as requested in counterclaim 1 of defendant AGA Medical Corporation’s answer and counterclaims [Docket No. 81], that

AGA Medical Corporation's accused devices and methods DO NOT
INFRINGE, directly or indirectly, U.S. Patent No. 6,077,291.

2. Defendant AGA Medical Corporation's motion for summary judgment of noninfringement [Docket No. 195] is DENIED in all other respects.
3. The Court construes disputed claim language as stated in the body of this order.

Dated: January 4, 2011

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge